UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,388	02/05/2004	Horst Georg Zerbe	2004-0189	3058

7590 03/03/2009

Michael R. Davis
WENDEROTH, LIND & PONACK
Suite 800
2033 "K" Street N.W.
Washington, DC 20006-1021

EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
03/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,388	ZERBE ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-29,31 and 33-61* is/are pending in the application.

4a) Of the above claim(s) *41-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-29,31,33-40 and 52-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed October 20, 2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)

1) Claims 10-23 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554) as applied to claims 24-29, 31, 33-36, 38-40 and 53-56 in further view of Story et al. (US 4,944,949). The rejection is maintained in regards to claims 10-23 and withdrawn in regards to claim 37. The rejection is further applied to claim 58.

Applicant's Arguments

Applicant argues the prior art teaches how a class of drug substances can be formulated to give micelle forming compositions using certain types of surfactants. The compounds of Majeti as well as the compositions of the instant claims absorb the active agent transmucosally and therefore there is no need to protect the gastrointestinal tract form the active ingredient as disclosed by Story et al.

Examiner's Response

Although the reference discloses NSAIDS, the surfactants are used not only for the formation of micelles but also for solubilizing NSAIDs. The reference teaches factors to consider when solubilizing NSAIDs that can be applied to solubilizing drugs in general. These factors include the hydrophilic-lipophilic balance (HLB), which may be applied when determining what surfactant is suitable for solubilizing a drug. Further the reference discloses mixtures of surfactants may be used to solubilize a drug. It is in the relative skill of one of ordinary skill in the art to use the teachings disclosed by Story et al. and apply them to formulations comprising a drug. Therefore it would have been obvious to use the surfactants and rationale of Story to solubilize the drugs used in the film formulations of Majeti. In regards to the drug being distributed uniformly throughout the film, the surfactants are also solubilizers and therefore when used to dissolve active compounds the compounds will be distributed uniformly throughout the film.

In regard to claim 58, Majeti discloses the use of plasticizers such as polyethylene glycol. Therefore the reference suggests the mixture as recited in claim 58.

2) Claims 30 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554) as applied to claims 24-29, 31, 33-36, 38-40 and 53-56 in further view of Stanley et al. (US 5,783,207). The rejection is maintained and further applied to claims 24-29, 31, 33-36, 38-40, 53-57 and 61.

Applicant's Arguments

Applicant argues nicotine salts are not readily absorbed through the mucosal membrane. According to Majeti, it is important that the two active components—nicotine and caffeine – are co-administered, therefore the skilled person would not have considered replacing nicotine with a salt thereof. Majeti is also silent in regards to using nicotine salts. Applicant concludes because caffeine and its derivatives were disclose as being suitable for the films of Majeti and the reference only discloses nicotine, and not its salts or derivatives, that this suggests that the salts of nicotine were not suitable for the films of the reference. One of skill in the art would not considering replacing nicotine with a nicotine salt and would have assumed that this salt would be absorbed only at insufficient rates, in relationship to caffeine which is co-administered. This argument is not persuasive.

Examiner's Response

Although the reference does not disclose nicotine salts, it does disclose nicotine's sensitivity to air and light. In order to overcome this, it is reasonable that one of ordinary skill in the art would use the salt because it is more stable, yet readily

converts to nicotine when exposed to the mouth. The disclosure that nicotine salt can readily convert to nicotine indicates that there would not be a great difference in the rate of release between nicotine and nicotine salts because nicotine salt are quickly converted to nicotine. Therefore it would not greatly affect the efficacy of the composition especially considering that caffeine has been disclosed to be slightly soluble and therefore would reasonably have a slower rate of release. Additionally the salts of caffeine may be used and would reasonably have faster rates of release than caffeine, but yet they may be used interchangeably. Therefore it is concluded that the salt of nicotine would not affect the efficacy of the compositions of Majeti.

In regards to claims 57 and 61, caffeine may be considered an awakening agent because it has a stimulating effect[1] and nicotine salicylate is disclosed by Stanley.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554) in further view of Stanley et al. (US 5,783,207) in further view of Story et al. (US 4,944,949).

Majeti and Stanley have been discussed in detail in the previous Office Actions. The references differ from the instant claims insofar as they do not disclose the compositions comprise a mixed surfactant system comprising polyoxyethylene sorbitan fatty acid ester or alpha-hydroxy-omega-hydroxypoly(oxyethylene)-

[1] Zeitlin et al. US 4076856, discloses caffeine has a stimulating effect.

poly(oxypropylene)poly(oxyethylene) block copolymer, and polyoxyethylene alkyl ether or a polyoxyethylene castor oil derivative.

Story et al is discussed in detail in the previous Office Action. The reference differs from the instant claims insofar as it does not disclose the oral compositions as a monolayer film or the oral compositions comprising water-soluble polymers.

It would have been obvious to one of ordinary skill in the art to have used the surfactants and mixtures thereof in the compositions of the combined teachings of the primary and secondary references motivated by the desire to ensure the desired pharmaceutical active agent was thoroughly dissolved and made a uniform mixture throughout the film as taught by the Story et al.

2) Claims 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554) in further view of Stanley et al. (US 5,783,207) in further view of Dam (US 5,733,574)..

Majeti and Stanley have been discussed in detail in the previous Office Actions. The references differ from the instant claims insofar as they do not disclose the compositions comprise caramel.

Dam discloses compositions for treating nicotine addiction. The compositions are formulated into gels and comprise nicotine or their salts. The compositions comprise coloring agents such as caramel, sweeteners, flavoring and stabilizing agents such as tartaric acid. The reference differs from the instant claims insofar as it does not disclose

the compositions are a monolayer films or the compositions comprising water-soluble polymers.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have incorporated caramel in the compositions of the combined teachings of Majeti and Stanley et al. motivated by the desire to use a coloring agent disclosed by the art as suitable for nicotine comprising compositions.

Claims 10-29, 31, 33-40 and 52-61 are rejected.

Claims 41-51 are withdrawn.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612